

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> :

A61M 25/00, 37/00, A61B 5/00, 6/00

A1

(11) International Publication Number:

WO 97/42996

(43) International Publication Date: 20 November 1997 (20.11.97)

(21) International Application Number: PCT/US97/05624

(22) International Filing Date: 3 April 1997 (03.04.97)

(30) Priority Data:

08/645,456

13 May 1996 (13.05.96)

US

(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published

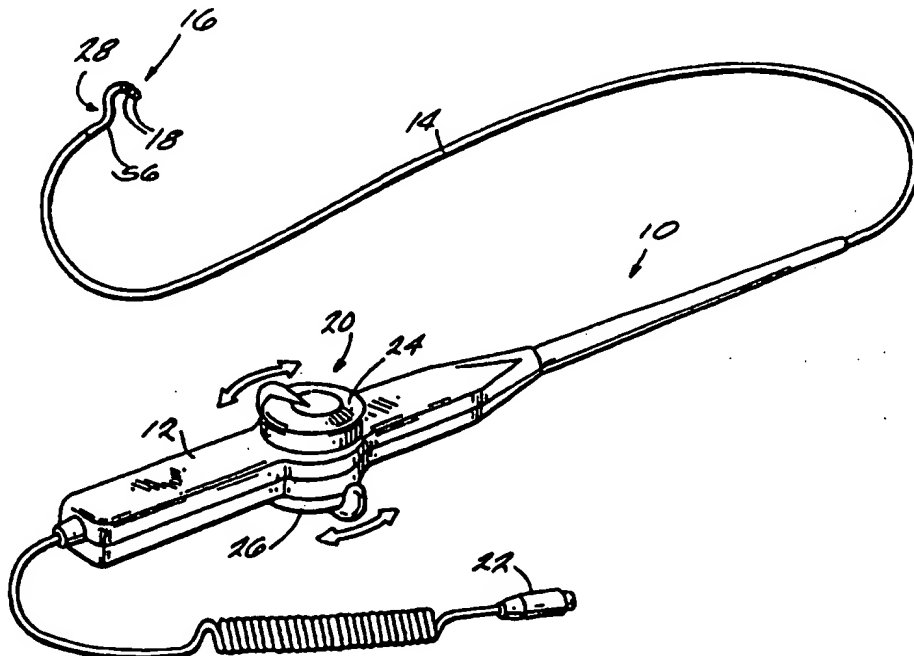
With international search report.

(71) Applicant: EP TECHNOLOGIES, INC. (US/US); Boston Scientific Corporation, 2710 Orchard Parkway, San Jose, CA 95134-2012 (US).

(72) Inventors: THOMPSON, Russell, B.; 123 West Portola Avenue, Los Altos, CA 94022 (US). FLEISCHMAN, Sidney, D.; 855 Woodland Avenue, Menlo Park, CA 94025 (US). WHAYNE, James, G.; 17930 Los Felice Road, Saratoga, CA 95070 (US). SWANSON, David, K.; 877 Heatherstone Way, Mountain View, CA 94040 (US).

(74) Agents: RYAN, Daniel, D. et al.; Suite 1900, 633 West Wisconsin Avenue, Milwaukee, WI 53203 (US).

(54) Title: ASSEMBLIES FOR CREATING COMPOUND CURVES IN DISTAL CATHETER REGIONS



(57) Abstract

Compound steering assemblies (28), usable in both diagnostic and therapeutic applications, enable a physician to swiftly and accurately steer the distal section (16) of the catheter (10) in multiple planes or complex curves to position and maintain ablation and/or mapping electrodes (18) in intimate contact with an interior body surface.



- 1 -

**ASSEMBLIES FOR CREATING COMPOUND  
CURVES IN DISTAL CATHETER REGIONS**

**Field of the Invention**

5        This invention relates to catheters that  
can be steered by external controls. More  
particularly the invention relates to such catheters  
that can assume complex three dimensional curves.  
In addition, the invention relates to the use of  
10       such complex curves to ablate arrhythmia substrates  
in body tissue.

**Background of the Invention**

15       Cardiac mapping is used to locate aberrant  
electrical pathways and currents emanating within  
the heart. Such aberrant pathways cause irregular  
contractions of the heart muscle resulting in life-  
threatening patterns or dysrhythmias.

20       Ablation of cardiac tissue to create long  
curvilinear lesions within the heart is also desired  
for treatment of various disorders such as atrial  
fibrillation. Various steering mechanisms for  
catheters carrying such electrodes have heretofore  
been developed and used.

25       To access various endocardial sites,  
physicians have used a number of different catheters  
and techniques, each of which provides a different  
characteristic. The use of catheters having limited  
steering characteristics increases the risk inherent  
in any catheterization procedure and limits the  
accessibility of many potential ablation sites.

30       Site access using standard distal tip

- 2 -

- 2 -

steerable catheters is less of a problem because those catheters position a single electrode into contact with the endocardium and a specific electrode orientation is not required. Problems of endocardial site access are accentuated when trying to simultaneously position multiple electrodes into intimate tissue contact. In this scenario, standard steerable catheter configurations orient multiple electrodes in planes emanating about the axis of the introduction vessel.

A need has thus existed for catheters which, in the nonlinear environment found within the heart as well as other body cavities, are capable of being steered to place ablation elements at a number of locations while creating intimate tissue contact throughout the length of all active ablation elements.

Particularly, a need has existed for a catheter which could effectively and accurately form curves in more than one plane for better access or tissue contact. Previous attempts to provide such devices are represented by U. S. Patent 5,383,852 wherein there was suggested the use of steering wire

extending from a central lumen of a catheter radially outward to the periphery of a distal end component.

Another suggestion is represented by U.S. Patent No. 5,358,479 wherein a single pull

cable is attached to the distal end of a shim which has two flat sections that are twisted relative to each other. This arrangement, however limits the device to bending, first, of the more distal portion of the shim followed by subsequent bending of the more proximal section, thus limiting the procedures using the device.

Summary of the Invention

35

- 5 -

- 3 -

The present invention provides a catheter, usable in both diagnostic and therapeutic applications, that enables a physician to swiftly and accurately steer the distal section of the catheter containing the ablation and/or mapping element(s) in multiple planes or complex curves within the body of a patient. The catheters that embody the invention allows physicians to better steer a catheter to access various endocardial sites. In its broadest aspect, the invention provides catheters which enable a physician to position ablation and/or mapping electrodes inserted within a living body by manipulation of external controls into intimate contact with an interior body surface that curves in more than one plane.

One aspect of the invention provides a catheter having more than one steering mechanism for bending the distal section by external manipulation into more than one curvilinear direction. Movement of the individual controls results in bending of the distal section at more than one location and in more than one direction. Thus the ease of accessing and measuring electrical activity in all portions of the heart is increased.

In accordance with another embodiment, the catheter steering assembly may include a proximal section containing a preformed portion in conjunction with a distal steering mechanism which enables steering in a different plane that is non-parallel to the bending plane of the preformed proximal section, and/or improving tissue contact by moving the focal point of the steering mechanism to increase the angle of steering capable of applying force against the endocardial surface. This configuration may be accomplished by preforming the

- 2 -

- 4 -

proximal section of the catheter into the desired curve or manipulating a preformed wire or other support structure which, when freed from the constraints of a sheath such as the catheter main body, causes the proximal section to assume the preformed shape.

In accordance with a further embodiment of the invention, a loop catheter has a preformed proximal end and a moveable wire attached to the distal end of the spline housing the ablation element(s). The preformed proximal end enables the loop to access varying planes relative to the catheter axis.

Further, objects and advantages of the invention will become apparent from the following detailed description and accompanying drawings.

#### Brief Description of Drawings

Fig. 1 is a perspective view of a catheter having a distal region with a compound steering assembly that embodies features of the invention;

Fig. 2 is a fragmentary side view of the handle portion of the catheter shown in Fig. 1;

Fig. 3 is a perspective view of one embodiment of a compound steering assembly that embodies features of the invention;

Fig. 4 is a side section view of another embodiment of a compound steering assembly that embodies features of the invention;

Figs. 5A to 5C are side views, with portions broken away and in section, of the compound steering assembly shown in Fig. 4 in use;

Figs. 6A to 6C are side views, with portions broken away and in section, of an alternative embodiment of a compound steering assembly that embodies features of the invention

- 4 -

- 5 -

being used;

Fig. 7 is an exploded perspective view of a two piece offset spring assembly that forms a part of an alternative embodiment of a compound steering assembly that embodies feature of the invention;

Figs. 8 and 9 are side perspective views of the compound steering assembly that incorporates the two piece offset spring assembly shown in Fig. 7;

Fig. 10A is a side view of another embodiment of a compound steering assembly that embodies features of the invention;

Fig. 10B is a top sectional view of the compound steering assembly shown in Fig. 10A, taken generally along line 10B-10B in Fig. 10A;

Fig. 11 is a side view of another embodiment of a compound steering assembly that embodies features of the invention;

Figs. 12 and 13 are side views of another embodiment of a compound steering assembly that embodies features of the invention;

Figs. 14 and 15 are side views of another embodiment of a compound steering assembly that embodies features of the invention;

Fig. 16 is a side view of a complex curve that a compound steering assembly made in accordance with the invention can assume;

Figs. 17 and 18 are side views of another embodiment of a compound steering assembly that embodies features of the invention; and

Figs. 19A to 19C are side views of another embodiment of a compound steering assembly that embodies features of the invention.

The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is

- 6 -

defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

#### Detailed Description of Preferred Embodiments

This Specification discloses electrode-carrying structures that can be bent in compound and complex manners for greater maneuverability within the body and enhanced contact with tissue. The illustrated and preferred embodiments discuss these structures, systems, and techniques in the context of catheter-based cardiac ablation. That is because these structures, systems, and techniques are well suited for use in the field of cardiac ablation.

Still, it should be appreciated that the invention is applicable for use in other tissue ablation applications. For example, the various aspects of the invention have application in procedures for ablating tissue in the prostate, brain, gallbladder, uterus, and other regions of the body, using systems that are not necessarily catheter-based.

Fig. 1 shows a catheter 10, which embodies features of the invention. The catheter 10 includes a handle 12 and a flexible catheter body 14. The distal region 16 of the catheter body 14 carries at least one electrode 18. In the illustrated and preferred embodiment, the distal region 16 carries an array of multiple electrodes 18.

The electrodes 18 can serve to monitor electrical events in heart tissue, or transmit electrical energy to ablate heart tissue, or both. Signal wires (not shown) are electrically coupled to the electrodes 18 in conventional fashion. The



- 3 -

- 7 -

signal wires extend through the catheter body 14 into the handle 12. The signal wires electrically connect to an exterior plug 22, which can be connected to signal processing equipment or a source of electrical ablation energy, or both.

The catheter 10 shown in Fig. 1 includes a steering mechanism 20. The mechanism 20 includes two control knobs 24 and 26 on the handle 12, which can be individually manipulated by the physician.

As will be described in greater detail later, the steering mechanism 20 is coupled to a compound steering assembly 28, which is carried within the distal region 16 of the catheter body 14. Operation of the control knobs 24 and 26 bend the steering assembly 28 to flex the distal region 16 (as Fig. 1 generally shows) in ways that aid in orienting the ablation element 18 in intimate contact with tissue.

Fig. 3 shows one embodiment of a compound steering assembly, designated by reference numeral 28(1), that embodies features of the invention. The compound steering assembly 28(1) includes a spring element formed as a single piece in two bendable sections 30 and 32. The bendable section 30 is distal to the bendable section 32.

In the illustrated embodiment, the bendable sections 30 and 32 are arranged essentially orthogonally relative to each other, being offset by about 90°. Different offset angles between 0° and 180° may be used.

The proximal end of the proximal bendable section 32 is secured within a guide tube 34. In the illustrated embodiment, the guide tube 34 takes the form of a coiled stainless steel spring. The guide tube 34 extends from the steering assembly

28(1) rearward within the catheter body 14 to the handle 12. The guide tube 34 serves to stiffen the catheter body 14 and to help impart twisting motion from the handle to the steering assembly 28(1).

As Fig. 3 shows, a distal steering wire 36 is attached by soldering or adhesive to one surface of the distal bendable section 30. The steering wire 36 extends from the bendable section 30 through a guide tube 38 secured by soldering or adhesive to a surface 40 of the proximal bendable section 32. From there, the steering wire 36 extends through the guide tube 34 into the handle 12. The steering wire 36 is coupled to the control knob 24 within the handle 12, as will be described in greater detail later.

A proximal steering wire 42 is attached by soldering or adhesive to the surface 44 of the proximal bendable section 32 opposite to the surface 40. From there, the steering wire 42 extends through the guide tube 34 into the handle 12. The steering wire 42 is coupled to the control knob 26 within the handle 12, as will be described in greater detail.

Flexible heat shrink tubing 56 (shown in Fig. 1 and in phantom lines in Fig. 3) encloses the compound steering assembly 28(1).

As Fig. 2 shows, the control knobs 24 and 26 are individually coupled by shafts, respectively 45 and 46, to rotatable cam wheels, respectively 48 and 50, within the handle 12. Rotation of the respective knob 24 and 26 serves to rotate its respective cam wheel 48 and 50. The steering wire 36 is attached to the cam wheel 48, and the steering wire 42 is attached to the cam wheel 50.

Further details of the structure of the cam wheels 48 and 50 and their attachment to the

- 8 -

- 9 -

steering wires 36 and 42 are not essential to the invention and can be found in United States Patent Number 5,254,088, which is incorporated herein by reference.

5                   Rotation of the cam wheel 48 (by manipulation of the knob 24) pulls upon the distal steering wire 36. This, in turn, pulls upon the distal bendable section 30, flexing the bendable section 30 in the direction of the wire 36 (shown by arrow 52 in Fig. 3). The guide tube 38 facilitates movement of the steering wire 36 and the transmission of the pulling force from the cam wheel 48 to the bendable section 30. In the absence of the pulling force upon the wire 36, the bendable section 30 resiliently returns to its normal unbent condition (shown in Fig. 3).

10                   Likewise, rotation of the cam wheel 50 (by manipulation of the knob 26) pulls upon the steering wire 42. This, in turn, pulls upon the proximal bendable section 32, flexing the bendable section 32 in the direction of the wire 42 (as arrow 54 shows in Fig. 3). In the absence of the pulling force upon the wire 42, the bendable section 32 resiliently returns to its normal unbent condition (as Fig. 3 shows).

15                   In the illustrated and preferred embodiment, the guide tube 38 comprises a stainless steel coil. As a steel coil, the guide tube 38 provides bending resistance and bias for the assembly 28(1) to return to the unbent orientation after deflection.

20                   The compound steering assembly 28(1) makes possible the formation of complex curves in the distal region 16. Pulling on the distal wire 36 bends the distal region 16 in the direction 52.

- 11 -

- 10 -

Pulling on the proximal steering wire 42 further bends the distal region 16 in a different direction 55.

Fig. 3 shows a single steering wire 36 and 42 attached to each bendable section 30 and 32 to provide unidirectional bending of each section 30 and 32. Of course, either or both bendable sections 30 and 32 may include an opposing pair of steering wires (not shown) to provide bidirectional bending

10 action. If bidirectional bending of the distal section 30 is desired, a guide tube 38 is preferably provided for each steering wire attached to the section 30. In this arrangement, the guide tubes should preferably comprise a material at least as 15 flexible as the proximal section 32 itself, so as to not impede the desired bending action.

Fig. 4 shows an alternative embodiment of a compound steering assembly, designated 28(2). The compound steering assembly 28(2) includes a spring 20 element formed as a single piece in two bendable sections 58 and 60. The bendable section 58 is distal to the bendable section 60.

Like the embodiment shown in Fig. 3, the proximal end of the bendable section 60 is secured 25 within a guide tube 34. Unlike the embodiment shown in Fig. 3, the bendable sections 58 and 60 are not offset from each other, but extend in the same plane.

A pair of steering wires 62 and 64 are 30 attached to opposite surfaces of the distal bendable section 58. The steering wires 62 and 64 extend rearward through the guide tube 34 within the catheter body 14 for attachment to opposite sides of a rotatable cam wheel (not shown) within the handle 35. United States Patent Number 5,254,088 shows the

5 details of this construction, which is incorporated herein by reference. Rotation of the cam wheel in one direction pulls on the steering wire 62 to bend the distal section 58 in one direction (shown by arrow 66A in Fig. 4). Rotation of the cam wheel in the opposite direction pulls on the steering wire 64 to bend the distal section 58 in the opposite direction (shown by arrow 66B in Fig. 6). Bi-directional steering of the distal section 58 is thereby achieved.

10 The compound steering assembly 28(2) shown in Fig. 4 further includes a preformed wire 68 secured by soldering or adhesive to the proximal bendable section 60. The preformed wire 68 is biased to normally curve. The preformed wire 68 may be made from stainless steel 17/7, nickel titanium, or other memory elastic material. It may be configured as a wire or as a tube with circular, elliptical, or other cross-sectional geometry.

15 20 The wire 68 normally imparts its curve to the attached bendable section 60, thereby normally bending the section 60 in the direction of the curve. The direction of the normal bend can vary, according to the functional characteristics desired. 25 The wire 68 can impart to the section a bend in the same plane as the distal bendable section 58 (as shown by arrow 66C in Fig. 4), or in a different plane.

30 In this arrangement, the steering assembly 28(2) further includes a main body sheath 70. The sheath 70 slides along the exterior of the catheter body 14 between a forward position overlying the junction between the wire 68 and proximal bendable section 60 and an aft position away from the proximal bendable section 68. In its forward 35

- 11 -

- 12 -

position, the sheath 70 retains the proximal bendable section 60 in a straightened configuration against the normal bias of the wire 68, as Fig. 4 shows. The sheath 70 may include spirally or helically wound fibers to provide enhanced tensile strength to the sheath 70. Upon movement of the sheath 70 to its aft position, the proximal bendable section 60 yields to the wire 68 and assumes its normally biased bent position. The slidable sheath 70 is attached to a suitable control mechanism on the handle 12.

As Fig. 5A shows, during introduction of the proximal catheter region 16 into the body, the sheath 70 is retained in its forward position. This retains the proximal bendable section 60 in a substantially straight orientation (as Fig. 4 also shows). After introduction of the distal catheter region 16 into a desired heart chamber, the sheath 70 is withdrawn (as shown in a stepwise fashion by Figs. 5B and 5C). The wire 68 urges the proximal bendable section 60 to assume a curvature in the direction indicated by arrow 66C.

The embodiment of Figs. 4 and 5A/B/C provides compound curves. The amount of curvature of the preshaped wire 68 is selected in accordance with the projected shape of the body chamber into which the catheter is introduced. Further bending of the distal section 58 is accomplished by pulling on the steering wires 62 and 64.

It should be appreciated that, instead of a stationary preshaped wire 68 and movable sheath 70, the steering assembly 28(2) can include a precurved stylet 72 (see Figs. 6A to 6C) moveable along the proximal bendable section 60 within a stationary sheath 74. A mechanism (not shown)

- SI -

- 13 -

mounted in the handle affects movement of the stylet 72 under the control of the physician. The stationary sheath 74 extends about the catheter body 14 up to distal region 16.

5 When located within the region of the sheath 74 (as Fig. 6A shows), the stylet 72 is retained by the sheath 74 in a straight condition. When the preshaped stylet 72 is advanced beyond the sheath 74 (as Figs. 6B and 6C show, the stylet 72 imparts its normal curve to the proximal section 60, causing it to assume a curvature determined by the stylet 72.

10 Figs. 7 to 9 show another alternative embodiment for a compound steering assembly, designated 28(3), embodying features of the invention. The compound steering assembly 28(3) includes a composite spring 76 formed from two individual spring sections 78 and 80 (see Fig. 7). The spring sections 78 and 80 include mating central notches 82 and 84, which nest one within the other to assemble the spring sections 78 and 80 together. Soldering or brazing secures the assembled sections 78 and 80 to complete the composite spring 76.

20 The resulting composite spring 76, like the spring shown in Fig. 3, comprises a bendable distal section 30 (spring section 78) and a bendable proximal section 32 (spring section 80). The bendable proximal section 32 is secured to a guide coil in the catheter body in the same manner shown in Fig. 3.

30 As Fig. 8 and 9 further show, the compound steering assembly 28(3) preferably includes two steering wires 86 and 88 attached by soldering or adhesive to opposite surfaces of the distal bendable section 30. The steering wires 86 and 88 each extend

- 21 -

- 14 -

from the distal bendable section 30 through a guide tube 90 secured by soldering or adhesive to one surface 92 of the proximal bendable section 32. From there, the steering wires 86 and 88 extend through the main guide tube 34 within the catheter body 14 into the handle 12 for attachment to a control mechanism in the handle, as already described.

As Figs. 8 and 9 also show, the compound steering assembly 28(3) preferably includes one steering wire 94 attached by soldering or adhesive to the proximal bendable section 32 on the surface opposite to the surface to which the guide tubes 90 are attached. The steering wire 94 likewise passes through guide tube 34 within the catheter body 14 for attachment to a second control mechanism in the handle, as already described.

As also previously described, the guide tubes 90 preferably take the form of metal coils. As coils, the guide tubes 90 provide increased spring bias to aid the return of the proximal bendable section 32 to the straightened position in the absence of pulling force on the steering wire.

The compound steering assembly 28(3) shown in Figs. 8 and 9 permits flexing the distal bendable section 30 in opposite directions normal to the surface of spring section 78. The compound steering assembly 28(3) also permits independent flexing of the proximal bendable section 32 in a single direction normal to the surface of spring section 80 to which the steering wire 94 is attached.

While the illustrated and preferred embodiment of the proximal bendable section 32 shown in Figs. 8 and 9 does not permit bidirectional bending, it should be appreciated that two oppositely attached steering wires may be attached



- 41 -

- 15 -

to the proximal section 32 to allow bidirectional steering. In this arrangement, the guide tubes 90 should be made of materials no less flexible than the proximal section itself.

Figs. 10A and 10B show another alternate embodiment of a compounding steering assembly, designated 28(4). The compound steering assembly 28(4) includes two separate steering assemblies 96 and 98 radially offset from each other within the catheter body 14 (see Fig. 10B). Each steering assembly 96 and 98 includes a bendable spring, respectively 100 and 102, carried by relatively small diameter spring coils, respectively 104 and 106. The bendable spring 100 extends distally to the bendable spring 102.

A pair of steering wires 108 and 110 are attached to the opposite sides of the distal steering spring 100 to enable bending in a first plane (shown by arrows 112 in Fig. 10A). A second pair of steering wires 114 and 116 are attached to opposite sides of the proximal steering spring 102 to enable bending in a second plane (shown by arrows 118 in Fig. 10A). As Fig. 10A shows, the small diameter wire coils 104 and 106 may themselves be contained within the larger diameter steering coil 34 within the catheter body 14.

Instead of steering wires 108/110 and 114/116, either or both springs 100 and 102 could be attached to preshaped wires (not shown) to assume a desired curvature, to thereby bend the respective spring in the manner shown in Fig. 4. Alternatively, the compound steering assembly 28(4) may include a third, preshaped wire section (not shown), like that shown in Fig. 4, located, either proximally or distally to the bendable springs 100 and 102. In

these arrangements, an external slidable sleeve (not shown) is used to selectively straighten the preshaped wire when desired. In this way, complex bends can be formed in the distal region in at least 3 different planes, or, alternatively, two bending locations can be provided in a single plane with another bending location being provided in an orthogonally separate plane.

Fig. 11 shows an alternative embodiment of a compound steering assembly, designated 28(5), that reduces stiffness of the proximal section. The compound steering assembly 28(5) includes two side-to-side guide coils 120 and 122. A distal element 124 is soldered between the distal ends of the guide coils 120 and 122, thereby collectively forming a distal bendable section 30. A PET retaining sleeve 126 preferably holds the guide coils 120 and 122 together orthogonal to plane of the distal element 124.

Distal steering wires 128 and 130 are attached to opposite sides of the distal element 124. The steering wires 128 and 130 pass through the guide coils 120 and 122 and into the main guide coil 34 within the catheter body 14 for attachment to a control element on the handle. By applying tension to a steering wire 128 and 130, the distal element 124 and guide coils 120 and 22 bend as a unified structure in the direction of the tensioned steering wire.

A proximal steering wire 132 is soldered to a transverse edge 134 of the distal element 124. The proximal steering wire 132 also extends into the main guide coil 34 within the catheter body 14 for attachment to another control element on the handle. By applying tension to the proximal steering wire

- 21 -

- 17 -

132, the distal element 124 and guide coils 120 and 122 bend as a unified structure in a direction orthogonal to the direction controlled by the distal steering wires 128 and 130. A second proximal steering wire (not shown) could be soldered to the opposite transverse edge of the distal element 124 for bi-directional steering.

Figs. 12 and 13 show another embodiment of a compound steering assembly, designated 28(6) that embodies features of the invention. The steering assembly 28(6) includes a preformed proximal section 136, which maintains a predefined curve, thereby forming a bend in the distal region 16. The distal end of the preformed proximal section 136 carries a ferrule 138. The ferrule 138 includes a notch 140. A bendable distal spring 142 fits within the notch 140.

The distal spring 142 includes two oppositely attached steering wires 144 and 146. Bi-directional bending of the spring 142 is thereby provided. Alternatively, a single steering wire could be provided for single directional bending.

A sleeve (not shown) made of Kevlar, polyester, or Kevlar Teflon, or plain polyester, preferably encircles the junction of the distal spring 142 and the ferrule 138 to strengthen the junction. Further details concerning the sleeve and the attachment of the spring to the distal end of the proximal section are contained in United States Patent 5,257,451, which is incorporated herein by reference.

As shown in Figs. 12 and 13, the notched ferrule 138 holds the distal spring 142 in a plane that is generally orthogonal to the plane of the preshaped bend of the preformed proximal section

The distal spring 142 therefore bends in two cross-plane directions, to the right and to the left of the proximal section 136 (as arrows 148 in Fig. 13 show). Still, it should be appreciated that the notched ferrule 138 can be rotated to hold the distal spring 142 in any desired angular relationship with the preshaped proximal section 136.

For example, Figs. 14 and 15 show the notch 140 of the ferrule 138 has been rotated to orient the distal spring 142 in generally the same plane as the preformed proximal section 136. In this arrangement, the distal spring 142 is supported for bi-directional, in-plane bending, upward and downward of the preformed proximal section (as arrows 150 in Fig. 15 show).

The proximal section 136 may be preformed into any desired curve, simple (as Figs. 12 and 13 show) or complex (as Fig. 16 shows, without a distal spring 142 attached).

In the illustrated simple and complex curve embodiments, the proximal section 136 preferably comprises a braid tube 152 made of polyamide with a wire braid, which is thermally formed into the desired shape. The preshaped proximal tube 152 preferably contains within it a guide coil 154, through which the steering wires 144/146 for the distal spring 142 pass. The steering wires 144/146 may also be preshaped like the proximal section to prevent straightening the preformed proximal section.

In the illustrated and preferred embodiments shown in Figs. 12 and 13 and Figs. 14 and 15, a flatwire 156 lends additional support to the preformed proximal section 136. The flatwire

- 81 -

- 19 -

156 is formed into a preshaped curve matching corresponding to the proximal section 136. The flatwire 156 is preferably bonded to the exterior of the proximal tube 152. Also preferably, an exterior polyester shrink tube 158 encloses the flatwire 156 and proximal tube 152 to hold them intimately together. The polyester shrink tube 158 can also serve this purpose without first bonding the flatwire 156 to the proximal tube 152. The assembly of the flatwire 156 and shrink tube 158 as just described can also be used in association with the complex curve shown in Fig. 16.

In an alternative embodiment (see Figs. 17 and 18), a compound steering assembly, designated 28(7), includes a proximal section 160 comprising a guide coil 166 that does not have a preset curvature. In this embodiment, the steering assembly 28(7) includes a flatwire 162 preshaped into the desired curve. The precurved flatwire 162 includes a bracket 164 at its distal end designed to receive and support the guide coil 166. The bracket 164 is spot welded to the guide coil 166, thereby holding the guide coil 166 in a bent condition corresponding to the curve of the flatwire 162. A heat shrink polyester tube (not shown) preferably encircles the flatwire 162 and guide coil 166 to hold them together. The preformed proximal section 136 is thereby formed.

The compound steering assembly 28(7) includes a notched ferrule 138 like that shown in the preceding Figs. 12 to 16. The ferrule 138 is spot welded to the distal end of the guide coil 166 (see Fig. 18) to receive and support a distal bendable spring 142 and steering wires 144 and 146, in the manner previously shown in Figs. 12 to 16. As

- 18 -

- 20 -

Before described, the notch 140 of the ferrule 138 can be rotated to orient the distal spring 142 in any desired orientation, either orthogonal to the curve axis of the preformed proximal section (as Fig. 18 and preceding Figs. 12 and 13 show), or in plane with the curve axis of the preformed proximal section (as preceding Figs. 14 and 15 show), or any desired angular relationship in between.

Instead of using a preformed braid tube 152 and/or a flatwire 156/162 to preform the proximal section 136 in the manner above described, the proximal section 136 may take the form of a malleable tube, which can be bent by the physician into the desired simple or complex curvature.

As Fig. 16 represents, the preformed proximal section 136 may be shaped in any simple 2-dimensional or complex 3-dimensional shape. Virtually any curvature can be selected for the proximal section end, provided that the curvature permits unimpeded movement of the steering wires 144/146 for the bendable distal spring 142. Furthermore, the stiffness of the preformed proximal section 136 is controlled so that it readily yields for straightening during introduction, either through the vasculature or a guide sheath.

In vivo experiments demonstrate that the walls of the vasculature themselves provide enough force to straighten the proximal section 136 made according to the invention, to thereby enable easy advancement of the distal region 16 of the catheter body 14 through the vasculature. Guide sheaths may also be used, if desired.

Entry of the distal region 16 of the catheter body 14 into the desired body cavity frees the proximal section 136, and it assumes its

- 05 -

- 21 -

predefined shape as previously described. The physician may now further manipulate the distal region 16 by rotating the catheter body 14 and/or bending the distal spring 142 to locate the ablation and/or sensing element(s) 18 at the desired tissue location(s).

The various compound steering assemblies 28(1) to 28(7) that the invention provides make it possible to locate the ablation and/or mapping electrode(s) at any location within the body cavity. With prior conventional catheter designs, various awkward manipulation techniques were required to position the distal region, such as prolapsing the catheter to form a loop within the atrium, or using anatomical barriers such as the atrial appendage or veins to support one end of the catheter while manipulating the other end, or torquing the catheter body. While these techniques can still be used in association with the compound assemblies 28(1) to 28(7), the compound bendable assemblies 28(1) to 28(7) significantly simplify placing electrode(s) at the desired location and thereafter maintaining intimate contact between the electrode(s) and the tissue surface. The compound assemblies 28(1) to 28(7) make it possible to obtain better tissue contact and to access previously unobtainable sites, especially when positioning multiple electrode arrays.

Compound bendable assemblies 28(1) to 28(7) which provide a proximal curved section orthogonal to the distal steering plane allow the physician to access sites which are otherwise difficult and often impossible to effectively access with conventional catheter configurations, even when using an anatomic barrier as a support structure. For example, to

- 22 -

- 22 -

place electrodes between the tricuspid annulus and the cristae terminalis perpendicular to the inferior vena cava and superior vena cava line, the distal tip of a conventional the catheter must be lodged in the right ventricle while the catheter is torqued and looped to contact the anterior wall of the right atrium. Compound bendable assemblies 28(1) to 28(7) which can provide a proximal curved section orthogonal to the distal steering plane greatly simplify positioning of electrodes in this orientation. Compound bendable assemblies 28(1) to 28(7) which provide a proximal curved section orthogonal to the distal steering plane also maintain intimate contact with tissue in this position, so that therapeutic lesions contiguous in the subepicardial plane and extending the desired length, superiorly and/or inferiorly oriented, can be accomplished to organize and help cure atrial fibrillation.

A transeptal approach will most likely be used to create left atrial lesions. In a transeptal approach, an introducing sheath is inserted into the right atrium through the use of a dilator. Once the dilator/sheath combination is placed near the fossa

ovalis under fluoroscopic guidance, a needle is inserted through the dilator and is advanced through the fossa ovalis. Once the needle has been confirmed to reside in the left atrium by fluoroscopic guidance of radiopaque contrast material injected through the needle lumen, the dilator/sheath combination is advanced over the needle and into the left atrium. At this point, the dilator is removed leaving the sheath in the left atrium.

A left atrial lesion proposed to help cure



atrial fibrillation originates on the roof of the left atrium, bisects the pulmonary veins left to right and extends posteriorly to the mitral annulus. Since the lesion described above is perpendicular to the transeptal sheath axis, a catheter which can place the distal steering plane perpendicular to the sheath axis and parallel to the axis of the desired lesion greatly enhances the ability to accurately place the ablation and/or mapping element(s) and ensure intimate tissue contact with the element(s). To create such lesions using conventional catheters require a retrograde procedure. The catheter is advanced through the femoral artery and aorta, past the aortic valve, into the left ventricle, up through the mitral valve, and into the left atrium. This approach orients the catheter up through the mitral valve. The catheter must then be torqued to orient the steering plane parallel to the stated lesion and its distal region must be looped over the roof of the left atrium to position the ablation and/or mapping element(s) bisecting the left and right pulmonary veins and extending to the mitral annulus. This awkward technique often fails to create adequate tissue contact necessary for therapeutic lesions.

Preformed guiding sheaths have also been employed to change catheter steering planes. However, preformed guiding sheaths have been observed to straighten in use, making the resulting angle different than the desired angle, depending on the stiffness of the catheter. Furthermore, a guiding sheath requires a larger puncture site for a separate introducing sheath, if the guiding sheath is going to be continuously inserted and removed. Additional transeptal punctures increase the

likelihood for complications, such as pericardial effusion and tamponade.

While various preferred embodiments of the invention have been shown for purposes of illustration it will be understood that those skilled in the art may make modifications thereof without departing from the true scope of the invention as set forth in the appended claims.

For example, as Figs. 19A to 19C show a  
10 compound loop assembly 168 carried at the distal end of a catheter body 14. The loop assembly 168 comprises at least two loop splines 168 and 170.

The loop spline 168 carries an array of ablation elements 172. According to the features of  
15 the invention described above, the loop spline 168 includes a proximal section 174 that is preformed into a desired curvature to access additional planes.

Since the loop spline 168 may be formed  
20 from memory elastic materials, the spline 168 may be preformed into any desired shape through mechanically forming the spline 168 and thermally forming the spline 168 in that shape. Preshaped braid tubing or other support may also be included  
25 to help maintain the shape of the proximal spline bend 174, as previously described.

As Figs. 19B and 19C show, the other spline 170 of the loop structure 168 may be retracted or advanced to decrease or increase the loop diameter  
30 to affect desired tissue contact and ablation element location.

The two splines 168 and 170 may be fabricated from a single wire made of nickel titanium or other memory elastic material.  
35 Alternatively, the two splines 168 and 170 may be

- AS -

- 25 -

fabricated from two or more wires which are connected by a distal tip at a common point. One spline may be attached to the catheter body, or two splines may be attached to the catheter body with another stylet to manipulate the preshaped loop, or both splines may be maneuvered.

Various features of the invention are set forth in the following claims.

**What is Claimed is:**

1. A steerable catheter comprising  
an elongated catheter body having a distal  
end; and

a single steering assembly carried by the  
distal end of the catheter tube including

a first steering mechanism for bending  
the distal end of the catheter body in a first  
plane, and

a second steering mechanism for  
bending the distal end of the catheter body in a  
second plane, which is non-parallel to the first  
plane.

2. A steerable catheter according to  
claim 1

wherein the second plane is substantially  
orthogonal to the first plane.

3. A steerable catheter according to  
claim 1

wherein the steering assembly is a spring  
structure, the first steering mechanism comprising  
a first section lying in a plane substantially  
perpendicular to the first plane and the second  
steering mechanism comprising a second section lying

in a plane substantially perpendicular to the second  
plane, the sections being axially displaced along  
the length of the spring structure with one of the  
first and second sections being distal to the other

wherein the steering assembly further  
includes a first steering wire attached to the first  
section and a second steering wire attached to the  
second section.

4. A steerable catheter according to  
claim 3

- 25 -

- 27 -

wherein the first and second sections comprise, respectively, first and second flattened sections.

5. A steerable catheter according to claim 4

and further including a handle attached to the proximal end of the catheter body, and

wherein proximal ends of the first and second steering wires are coupled to the handle.

6. A steerable catheter according to claim 4

wherein the first and second flattened sections are coupled together to form a unitary spring structure.

7. A steerable catheter according to claim 4

wherein the steering assembly further includes a third steering wire attached to the first flattened section and a fourth steering wire attached to the second flattened section.

8. A steerable catheter according to claim 4

and further including a guide tube carried by the catheter body enclosing the first and second steering wires.

9. A steerable catheter according to claim 4

and further including a coil spring carried by the catheter body proximate to the distal end, the coil spring having an interior lumen extending along the length of the catheter body and a distal end affixed to the proximal one of the first and second flattened sections.

10. A steerable catheter according to claim 1

- 28 -

wherein the first steering mechanism comprises a preshaped wire biased to bend the distal end of the catheter into a curvilinear shape in the first plane.

5 10. A steerable catheter according to claim 9

wherein the preshaped wire is located proximally to the second steering mechanism.

11. A steerable catheter according to claim 9

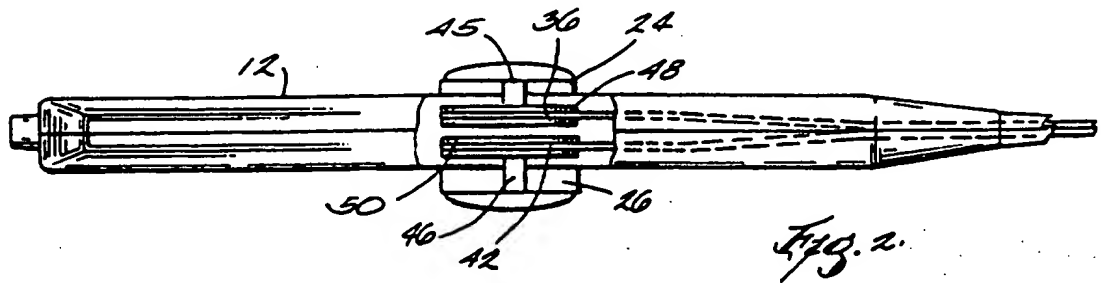
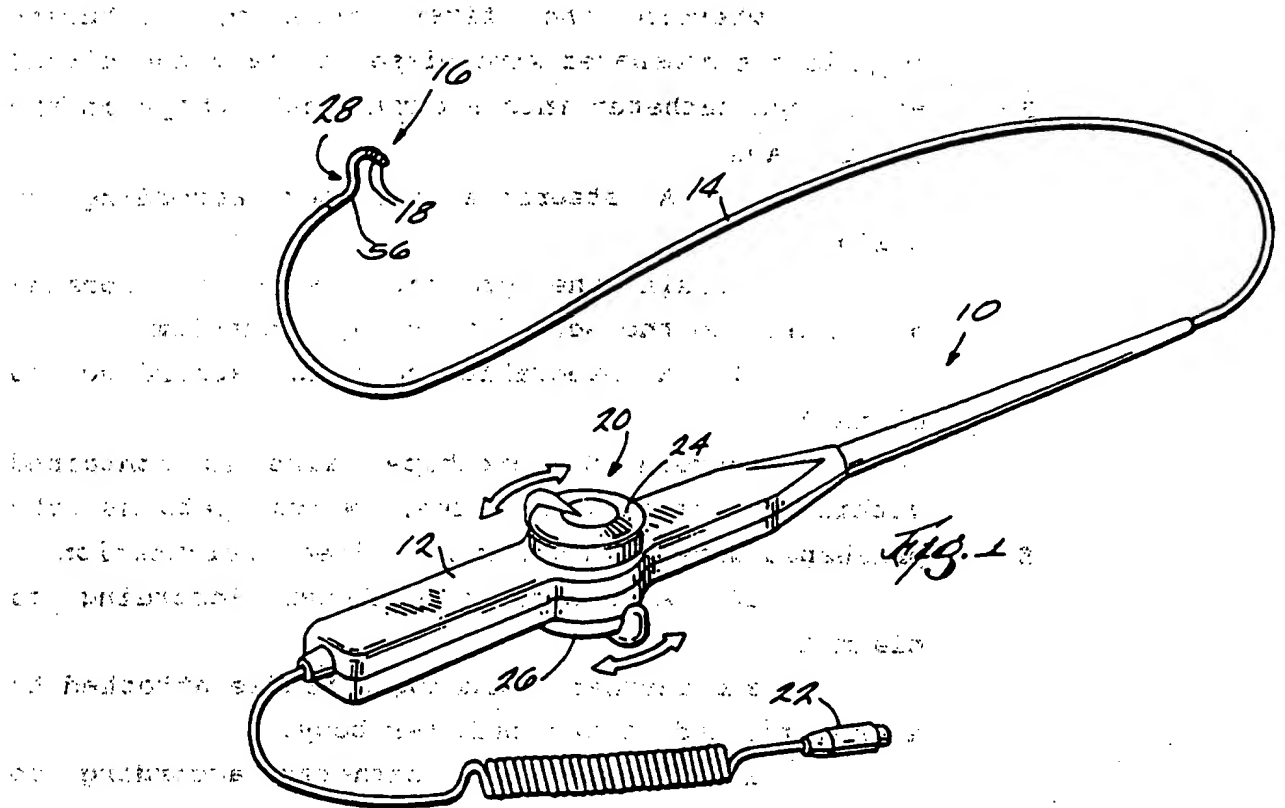
5 wherein the preshaped wire is contained within an introducer tube, which retains the preshaped wire in a generally linear orientation.

12. A steerable catheter according to claim 1

and further including a handle attached to a proximal end of the catheter body.

13. A steerable catheter according to claim 1

and further including a functional element carried by the distal end of the catheter body.



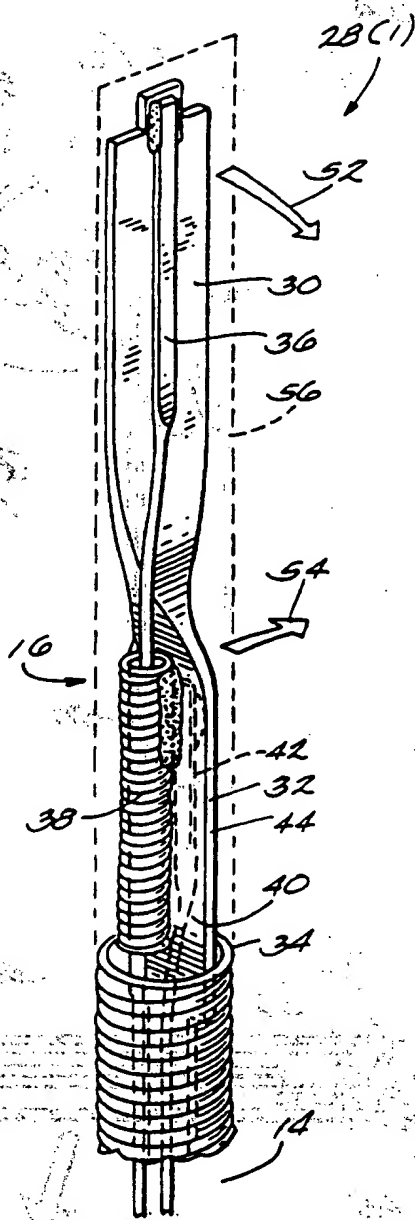


Fig. 3

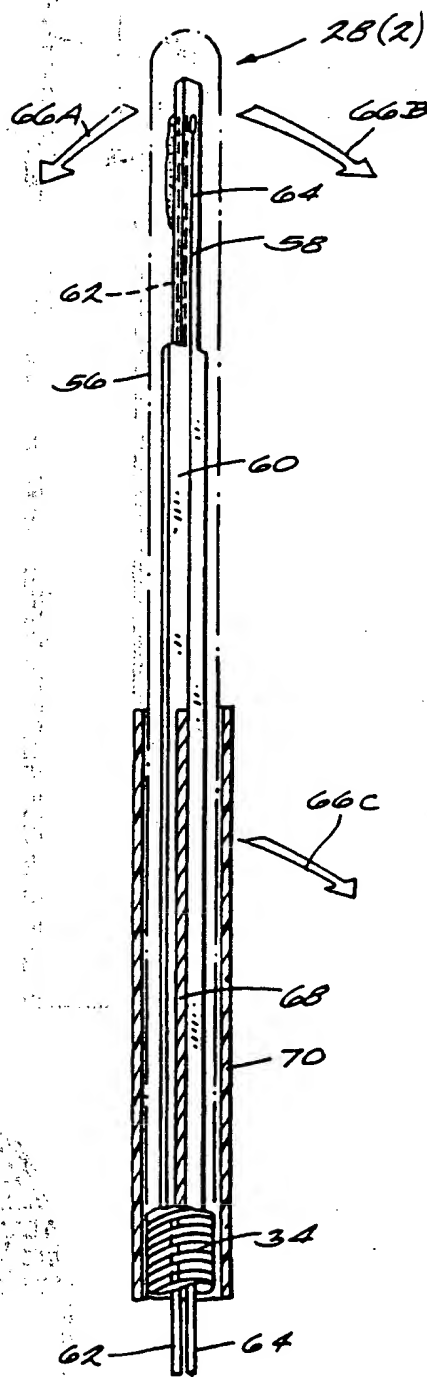
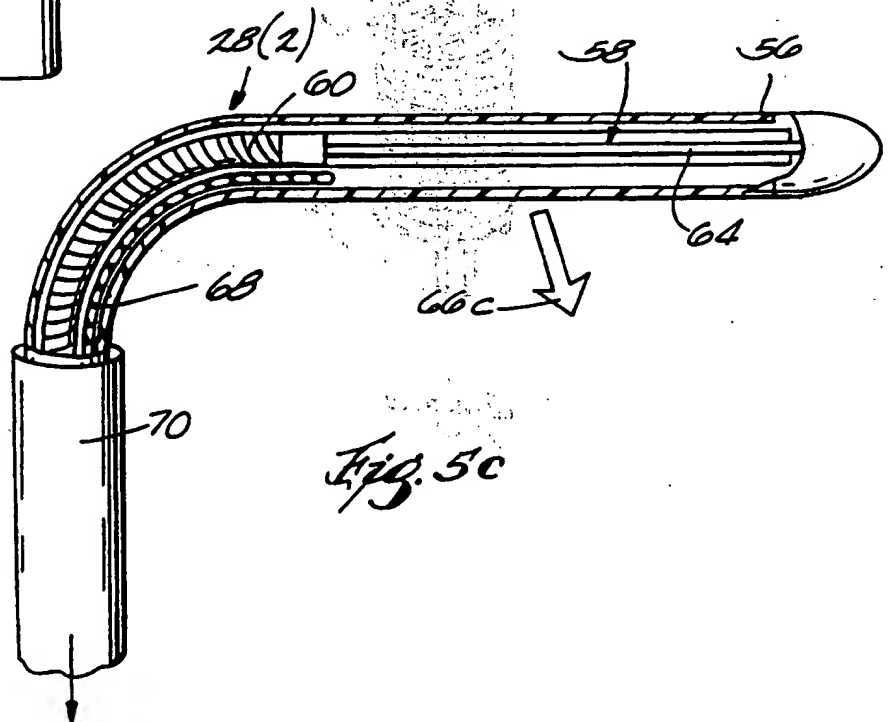
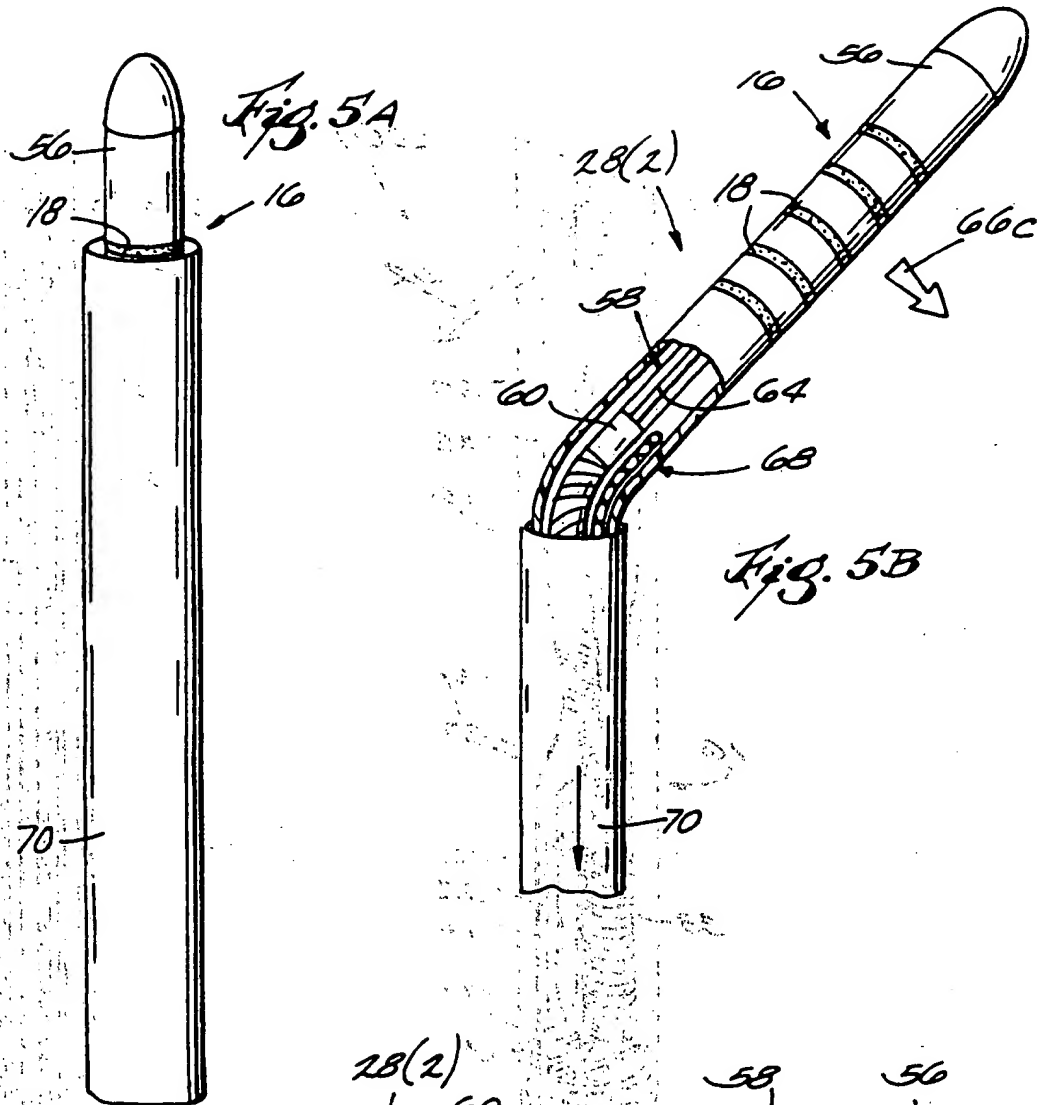
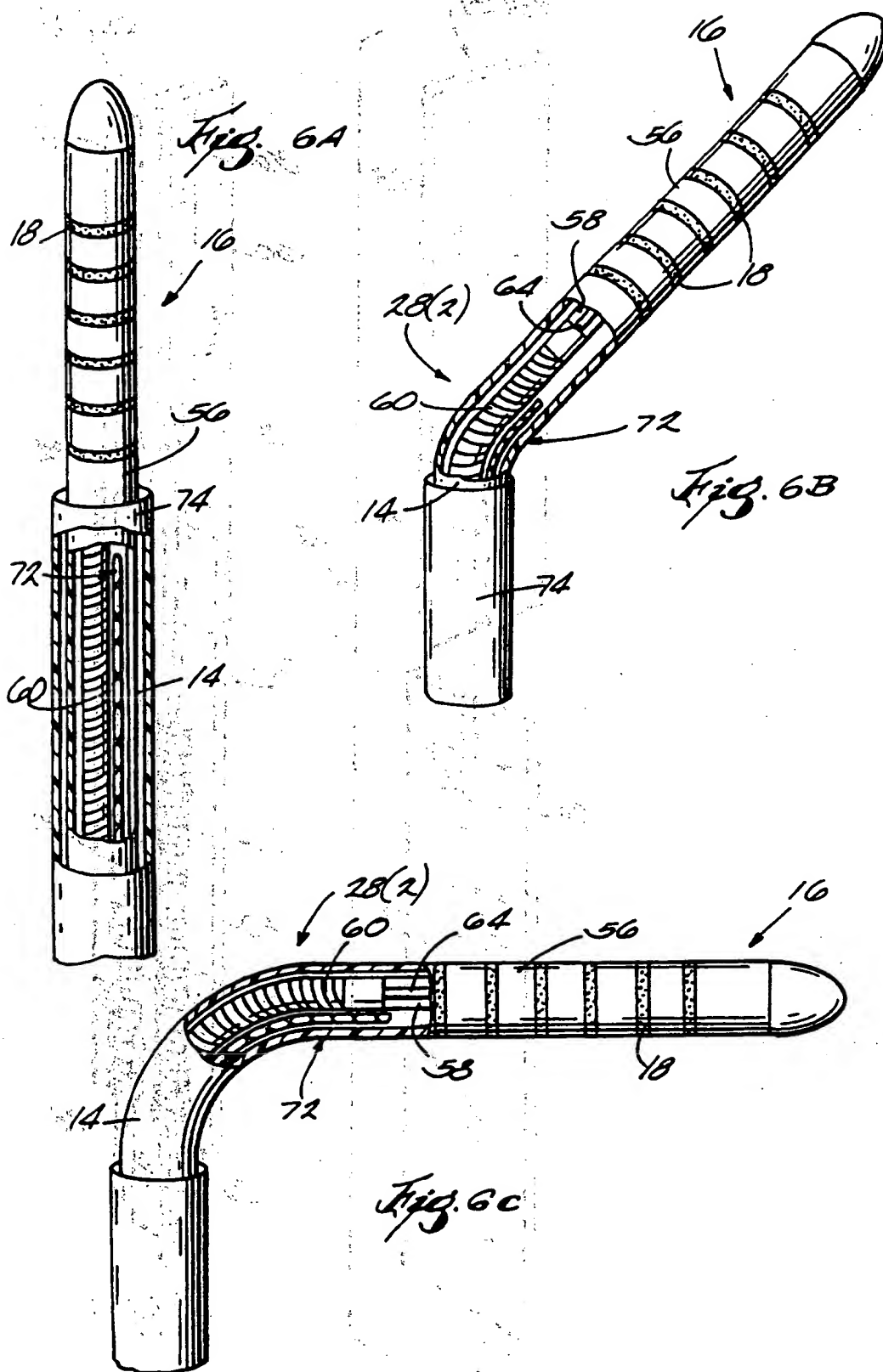


Fig. 4

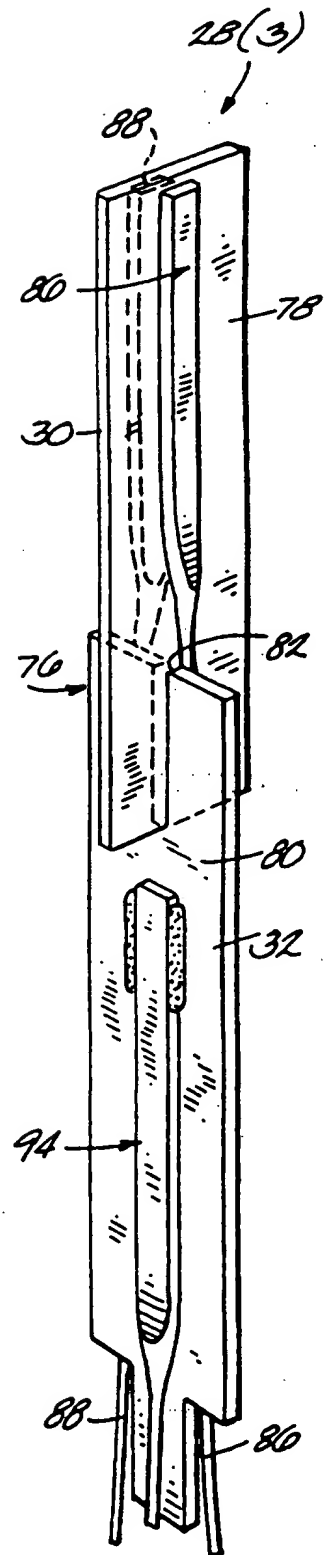
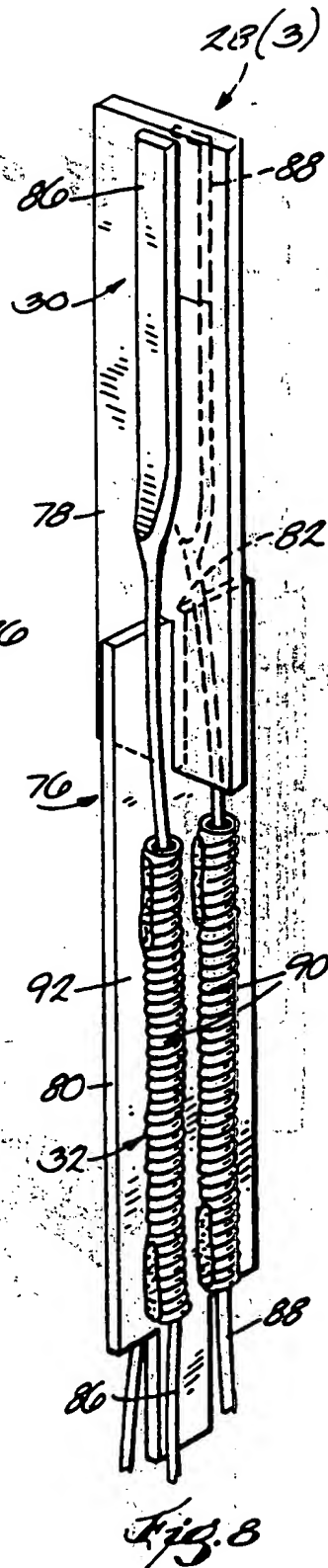
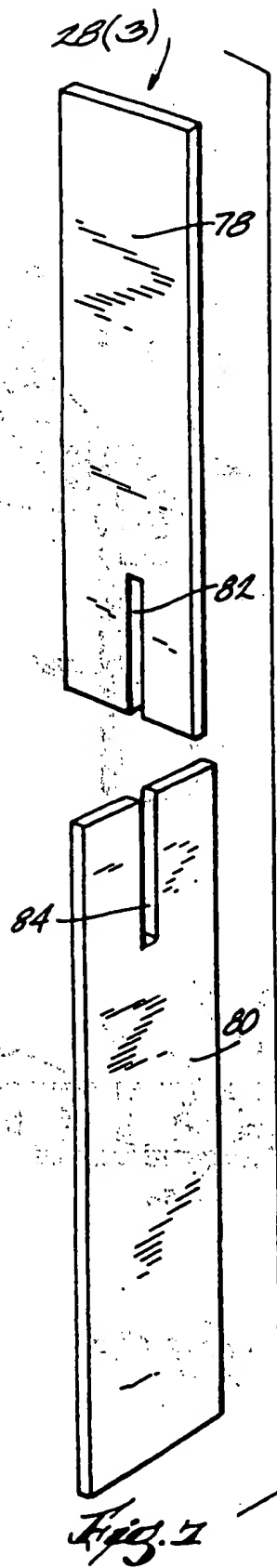


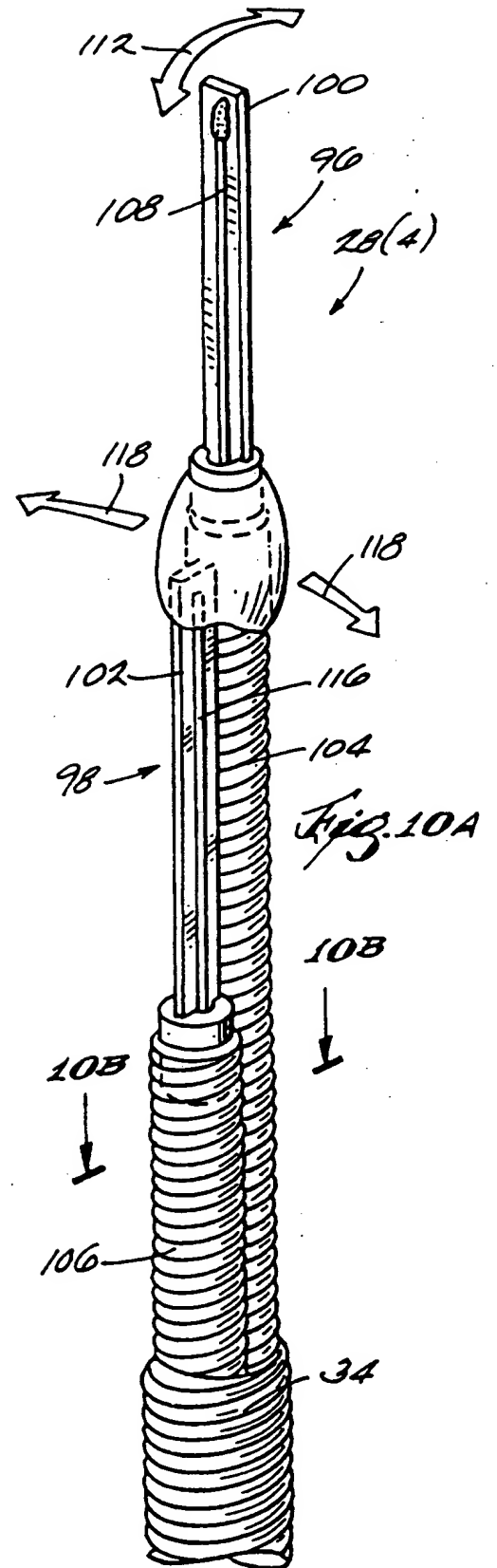
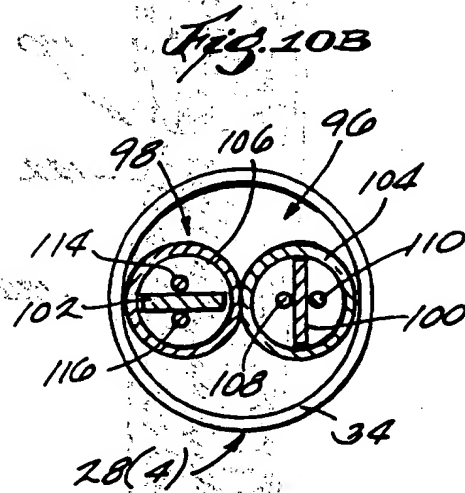


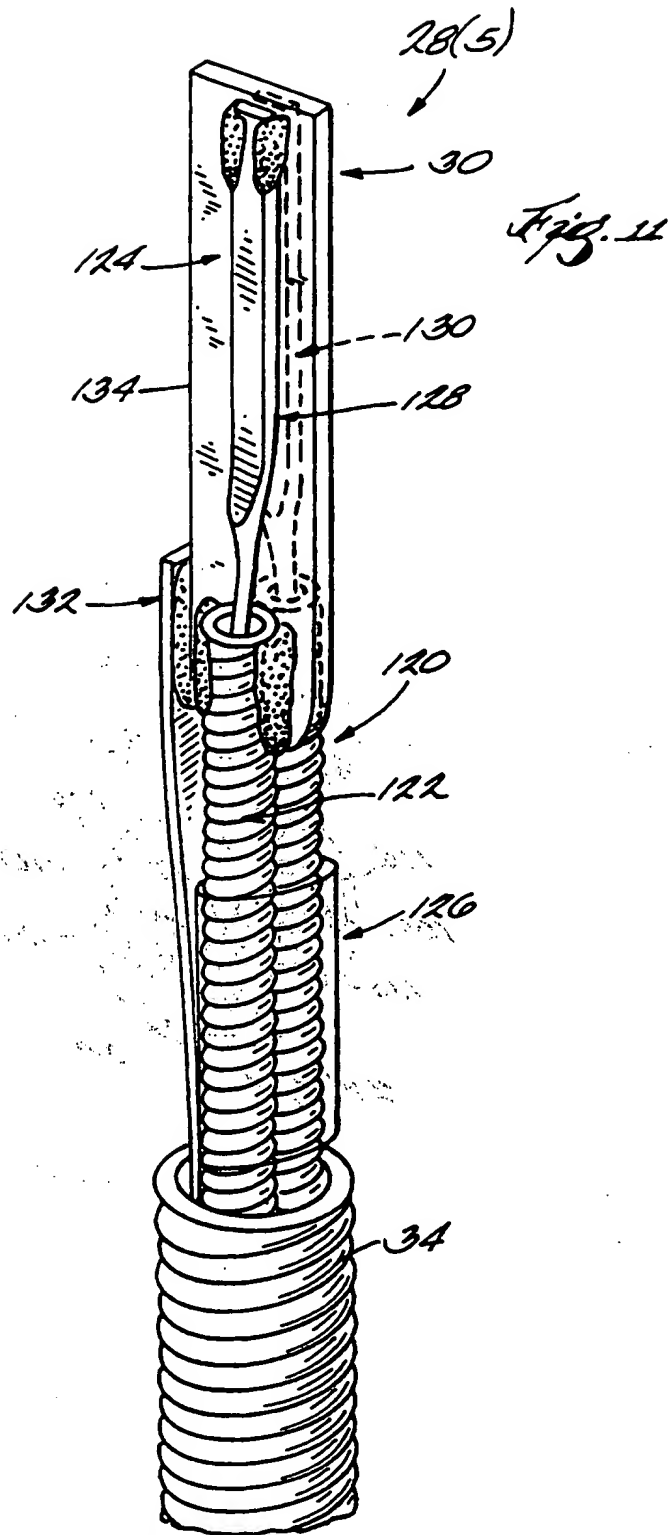
4/11

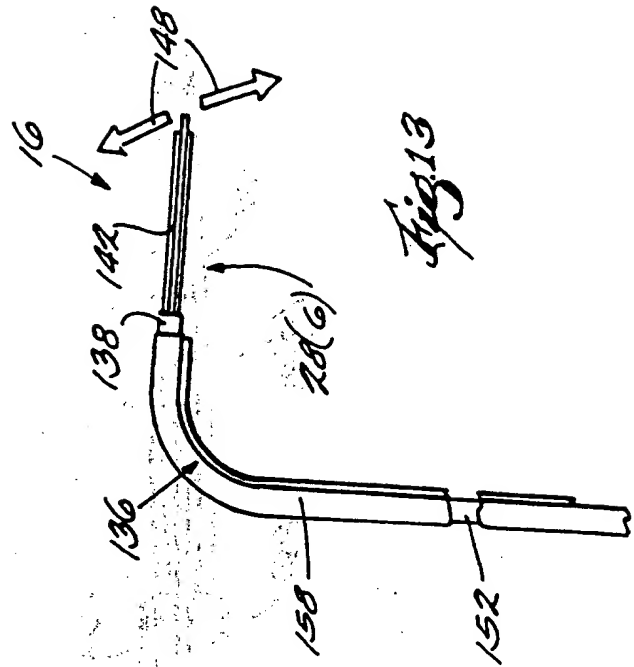


5/11









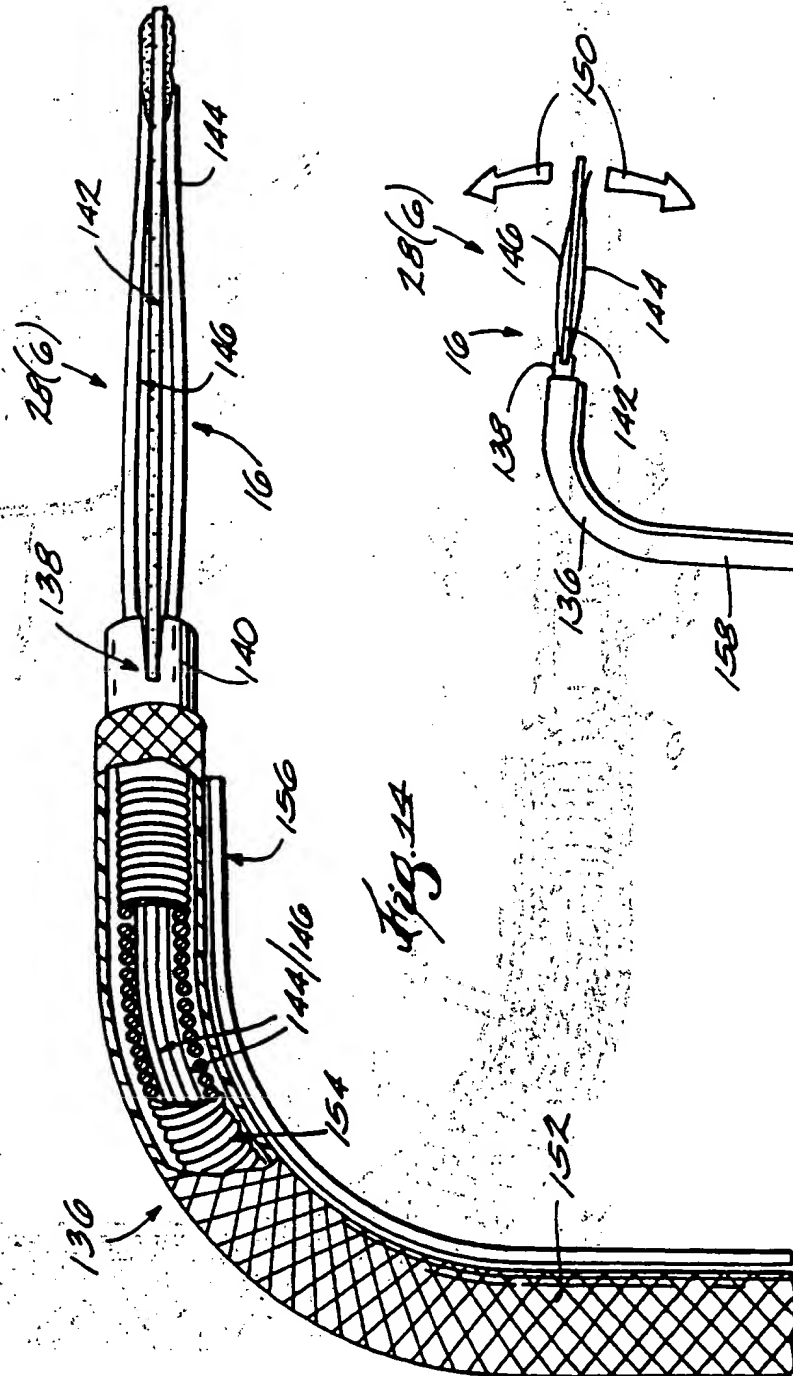


Fig. 14

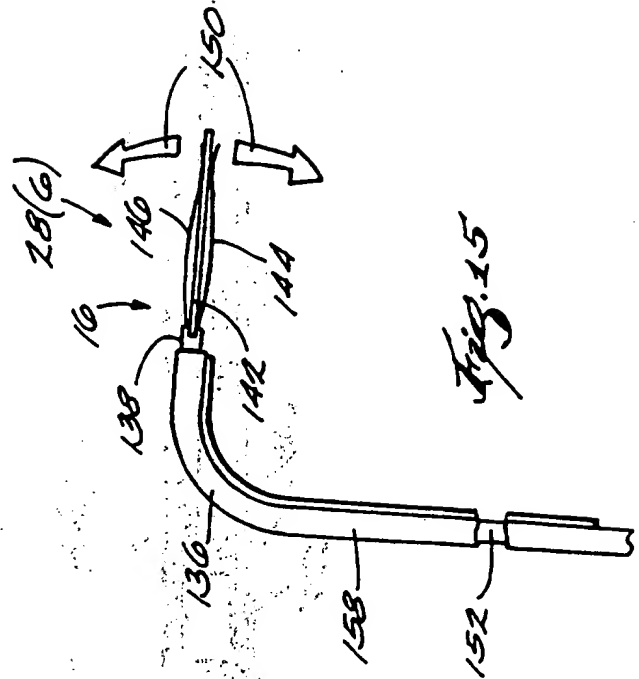
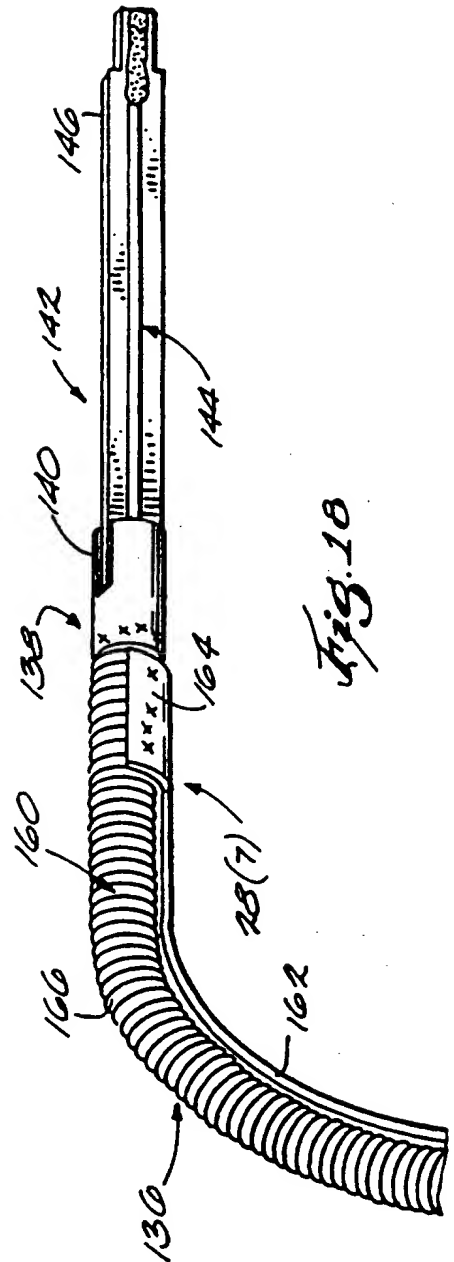
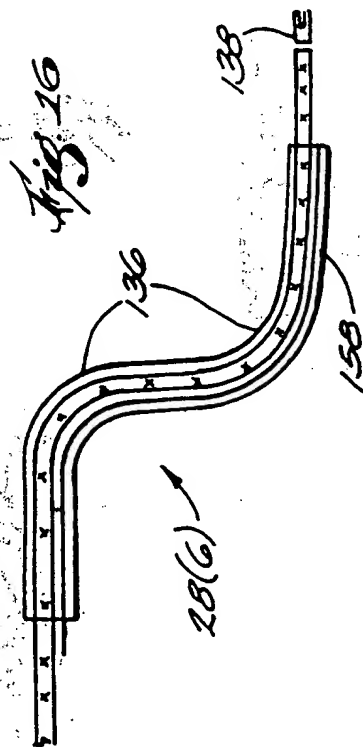
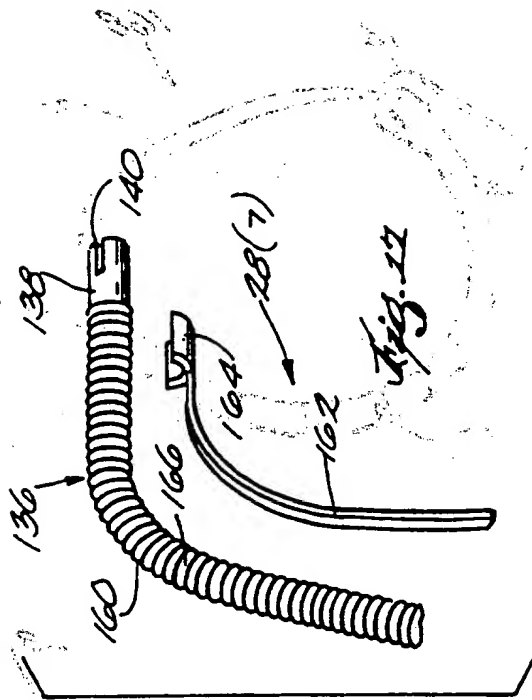


Fig. 15

10/11

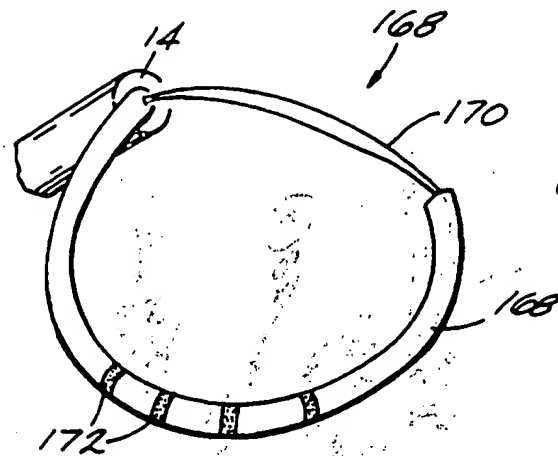
11/11



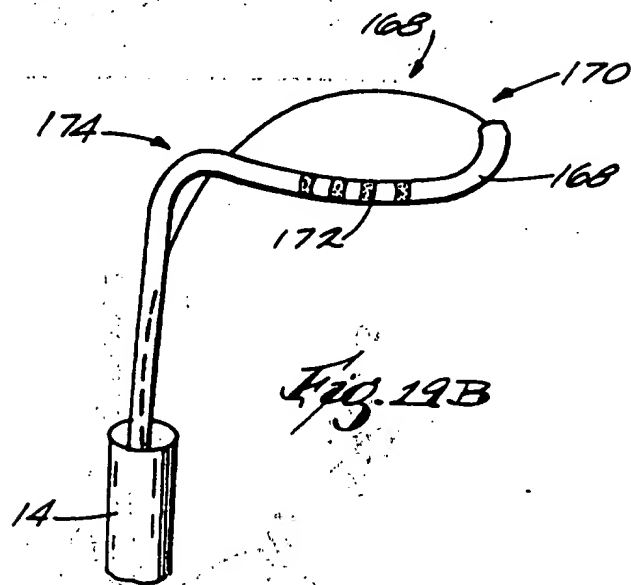


11/01

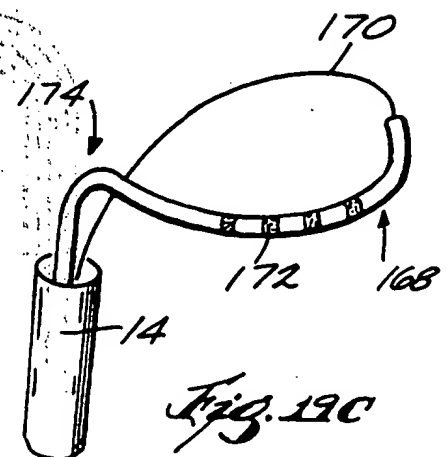
11/11



*Fig. 19A*



*Fig. 19B*



*Fig. 19C*

# INTERNATIONAL SEARCH REPORT

International application No. PCT/US97/05624

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 25/00; 37/00; A61B 5/00, 6/00  
US CL : 128/657, 772; 604/95

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. 604/95, 164, 280, 281, 282; 128/656, 657, 658, 772

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
none

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
none

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,358,479 A (WILSON) 25 October 1994, Fig. 4, and col.9 line 8 to col. 10 line 15.	1, 2, 9-13 ----- 3-6, 8
Y	US 5,190,050 A (NITZSCHE) 02 March 1993, Figs. 4-6, and col. 5 line 50 to col. 6 line 3.	3-6, 8
A	US 5,273,535 A (EDWARDS et al) 28 December 1993.	10
A,P	US 5,571,085 A (ACCISANO, III) 05 November 1996.	10



Further documents are listed in the continuation of Box C.



See patent family annex.

### Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document published on or after the international filing date
- \*L\* document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later documents published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

09 MAY 1997

Date of mailing of the international search report

25 JUN 1997

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized Officer

BHISMA MEHTA

Telephone No. (703) 305-7350